

Preliminary Classification:

Proposed Class:

Subclass:

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example "Proposed Class 2, subclass 129." M.P.E.P. § 601, 7th ed.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application

Assistant Commissioner for Patents

Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): ROBERT BRUCE SPERTELL

WARNING: 37 C.F.R. § 1.41(a)(1) points out:

"(a) A patent is applied for in the name or names of the actual inventor or inventors.

"(f) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by § 1.63, except as provided for in § 1.53(d)(4) and § 1.63(d). If an oath or declaration as prescribed by § 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to § 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in § 1.17(i) is filed supplying or changing the name or names of the inventor or inventors."

For (title): METHOD AND APPARATUS FOR TREATING SUBCUTANEOUS HISTOLOGICAL FEATURES

CERTIFICATION UNDER 37 C.F.R. § 1.10***(Express Mail label number is mandatory.)****(Express Mail certification is optional.)**

I hereby certify that this New Application Transmittal and the documents referred to as attached therein are being deposited with the United States Postal Service on this date _____, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number _____, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

(type or print name of person mailing paper)

Signature of person mailing paper

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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1c803 U.S. PTO
08/14/00

08/14/00
09/637923
J-C803 U.S. PTO

09/637923-081400

1. Type of Application

This new application is for a(n)

(check one applicable item below)

- ☐ Original (nonprovisional)
☐ Design
☐ Plant

WARNING: Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. § 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

WARNING: Do not use this transmittal for the filing of a provisional application.

NOTE: If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

- ☒ Divisional.
☐ Continuation.
☐ Continuation-in-part (C-I-P).

2. Benefit of Prior U.S. Application(s) (35 U.S.C. §§ 119(e), 120, or 121)

NOTE: A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. § 112. Each prior application must also be:

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) Complete as set forth in § 1.51(b); or

(iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or

(iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(f) within the time period set forth in § 1.53(f).

37 C.F.R. § 1.78(a)(1).

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. §§ 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. §§ 120, 121 or 365(c). (35 U.S.C. § 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. §§ 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

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004780.22672966

WARNING: When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional application **must** be filed prior to the Saturday, Sunday, or Federal holiday within the District of Columbia. See 37 C.F.R. § 1.78(a)(3).

- ☐ The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

3. Papers Enclosed

- A.** Required for filing date under 37 C.F.R. § 1.53(b) (Regular) or 37 C.F.R. § 1.153 (Design) Application

25 Pages of specification

11 Pages of claims

8 Sheets of drawing

WARNING: **DO NOT** submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. § 1.84, see Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE: "Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page" 37 C.F.R. § 1.84(c).

(complete the following, if applicable)

- ☐ The enclosed drawing(s) are photograph(s), and there is also attached a "PETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)." 37 C.F.R. § 1.84(b).
- ☒ formal
- ☐ informal

B. Other Papers Enclosed

3 Pages of declaration and power of attorney

1 Pages of abstract

Other

4. Additional papers enclosed

- ☒ Amendment to claims
- ☒ Cancel in this applications claims 8-19 before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
- ☐ Add the claims shown on the attached amendment. (Claims added have been numbered consecutively following the highest numbered original claims.)
- ☐ Preliminary Amendment
- ☐ Information Disclosure Statement (37 C.F.R. § 1.98)
- ☐ Form PTO-1449 (PTO/SB/08A and 08B)
- ☐ Citations

- ☐ Declaration of Biological Deposit
- ☐ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.
- ☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative
- ☐ Special Comments
- ☐ Other

5. Declaration or oath (including power of attorney)

NOTE: A newly executed declaration is not required in a continuation or divisional application provided that the prior nonprovisional application contained a declaration as required, the application being filed is by all or fewer than all the inventors named in the prior application, there is no new matter in the application being filed, and a copy of the executed declaration filed in the prior application (showing the signature or an indication thereon that it was signed) is submitted. The copy must be accompanied by a statement requesting deletion of the names of person(s) who are not inventors of the application being filed. If the declaration in the prior application was filed under § 1.47, then a copy of that declaration must be filed accompanied by a copy of the decision granting § 1.47 status or, if a nonsigning person under § 1.47 has subsequently joined in a prior application, then a copy of the subsequently executed declaration must be filed. See 37 C.F.R. §§ 1.63(d)(1)-(3).

NOTE: A declaration filed to complete an application must be executed, identify the specification to which it is directed, identify each inventor by full name including family name and at least one given name, without abbreviation together with any other given name or initial, and the residence, post office address and country or citizenship of each inventor, and state whether the inventor is a sole or joint inventor. 37 C.F.R. § 1.63(a)(1)-(4).

NOTE: "The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by § 1.62, except as provided for in § 1.53(d)(4) and § 1.63(d). If an oath or declaration as prescribed by § 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to § 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in § 1.17(i) is filed supplying or changing the name or names of the inventor or inventors." 37 C.F.R. § 1.41(a)(1).

☒ Enclosed

Executed by

(check all applicable boxes)

☒ inventor(s).

☐ legal representative of inventor(s).
37 C.F.R. §§ 1.42 or 1.43.

☐ joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

☐ This is the petition required by 37 C.F.R. § 1.47 and the statement required by 37 C.F.R. § 1.47 is also attached. See item 13 below for fee.

☐ Not Enclosed.

NOTE: Where the filing is a completion in the U.S. of an International Application or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.

☐ Application is made by a person authorized under 37 C.F.R. § 1.41(c) on behalf of all the above named inventor(s).

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(The declaration or oath, along with the surcharge required by 37 C.F.R. § 1.16(e) can be filed subsequently).

- ☐ Showing that the filing is authorized.
(not required unless called into question. 37 C.F.R. § 1.41(d))

6. Inventorship Statement

WARNING: If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.

The inventorship for all the claims in this application are:

- ☒ The same.

or

- ☐ Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,
☐ is submitted.
☐ will be submitted.

7. Language

NOTE: An application including a signed oath or declaration may be filed in a language other than English. An English translation of the non-English language application and the processing fee of \$130.00 required by 37 C.F.R. § 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 C.F.R. § 1.52(c).

- ☒ English
☐ Non-English
☐ The attached translation includes a statement that the translation is accurate. 37 C.F.R. § 1.52(d).

8. Assignment

- ☒ An assignment of the invention to _____
Microwave Medical Corporation Simi Valley CA
☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.
☐ will follow.

NOTE: "If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: A newly executed "CERTIFICATE UNDER 37 C.F.R. § 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.

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- ☒ Was Filed in Parent Application 08/904,175

08637923-004400

9. Certified Copy

Certified copy(ies) of application(s)

Country	Appln. No.	Filed
Country	Appln. No.	Filed
Country	Appln. No.	Filed

from which priority is claimed

- ☐ is (are) attached.
☐ will follow.

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 C.F.R. § 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. § 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 C.F.R. § 1.16)

A. ☒ Regular application

CLAIMS AS FILED				
Number filed		Number Extra	Rate	Basic Fee 37 C.F.R. § 1.16(a) \$690.00
Total				
Claims (37 C.F.R. § 1.16(c))	50 - 20 =	30	× \$ 18.00	\$540
Independent				
Claims (37 C.F.R. § 1.16(b))	9 - 3 =	6	× \$ 78.00	\$468
Multiple dependent claim(s), if any (37 C.F.R. § 1.16(d))			+ \$260.00	

- ☐ Amendment cancelling extra claims is enclosed.
☐ Amendment deleting multiple-dependencies is enclosed.
☐ Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 C.F.R. § 1.16(d).

Filing Fee Calculation \$ 1698

B. ☐ Design application
(\$310.00—37 C.F.R. § 1.16(f))

Filing Fee Calculation \$

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- C. ☐ Plant application
(\$480.00—37 C.F.R. § 1.16(g))

Filing fee calculation

\$ _____

11. Small Entity Statement(s)

- ☐ Statement(s) that this is a filing by a small entity under 37 C.F.R. § 1.9 and 1.27 is (are) attached.

WARNING: "Status as a small entity must be specifically established in each application or patent in which the status is available and desired. Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. The refiling of an application under § 1.53 as a continuation, division, or continuation-in-part (including a continued prosecution application under § 1.53(d)), or the filing of a reissue application requires a new determination as to continued entitlement to small entity status for the continuing or reissue application. A nonprovisional application claiming benefit under 35 U.S.C. § 119(e), 120, 121, or 365(c) of a prior application, or a reissue application may rely on a statement filed in the prior application or in the patent if the nonprovisional application or the reissue application includes a reference to the statement in the prior application or in the patent or includes a copy of the statement in the prior application or in the patent and status as a small entity is still proper and desired. The payment of the small entity basic statutory filing fee will be treated as such a reference for purposes of this section." 37 C.F.R. § 1.28(a)(2).

WARNING: "Small entity status must not be established when the person or persons signing the . . . statement can unequivocally make the required self-certification." M.P.E.P., § 509.03, 6th ed., rev. 2, July 1996 (emphasis added).

(complete the following, if applicable)

- ☒ Status as a small entity was claimed in prior application

08 / 904,175 filed on July 31, 1997, from which benefit is being claimed for this application under:

- 35 U.S.C. § ☐ 119(e),
☒ 120,
☒ 121,
☐ 365(c),

and which status as a small entity is still proper and desired.

- ☐ A copy of the statement in the prior application is included.

Filing Fee Calculation (50% of **A, B or C** above)

\$ 849.00

NOTE: Any excess of the full fee paid will be refunded if small entity status is established and a refund request are filed within 2 months of the date of timely payment of a full fee. The two-month period is not extendable under § 1.136. 37 C.F.R. § 1.28(a).

12. Request for International-Type Search (37 C.F.R. § 1.104(d))

(complete, if applicable)

- ☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made at This Time

- ☐ Not Enclosed
- ☐ No filing fee is to be paid at this time.
(This and the surcharge required by 37 C.F.R. § 1.16(e) can be paid subsequently.)
- ☒ Enclosed
- ☒ Filing fee \$ 849
- ☐ Recording assignment
(\$40.00; 37 C.F.R. § 1.21(h))
(See attached "COVER SHEET FOR
ASSIGNMENT ACCOMPANYING NEW
APPLICATION".) \$
- ☐ Petition fee for filing by other than all the
inventors or person on behalf of the inventor
where inventor refused to sign or cannot be
reached
(\$130.00; 37 C.F.R. §§ 1.47 and 1.17(i)) \$
- ☐ For processing an application with a
specification in
a non-English language
(\$130.00; 37 C.F.R. §§ 1.52(d) and 1.17(k)) \$
- ☐ Processing and retention fee
(\$130.00; 37 C.F.R. §§ 1.53(d) and 1.21(l)) \$
- ☐ Fee for international-type search report
(\$40.00; 37 C.F.R. § 1.21(e)) \$

NOTE: 37 C.F.R. § 1.21(f) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 C.F.R. § 1.53(f) and this, as well as the changes to 37 C.F.R. §§ 1.53 and 1.78(a)(1), indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of § 1.21(f) must be paid, within 1 year from notification under § 53(f).

Total fees enclosed \$ 849

14. Method of Payment of Fees

- ☒ Check in the amount of \$ 849
- ☐ Charge Account No. _____ in the amount of \$ _____
- A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).

15. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing, the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

- ☒ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 10-1213:

☒ 37 C.F.R. § 1.16(a), (f) or (g) (filing fees)

☒ 37 C.F.R. § 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☐ 37 C.F.R. § 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

☐ 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a)).

☐ 37 C.F.R. § 1.17 (application processing fees)

NOTE: "... A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: 37 C.F.R. § 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . the issue fee. . . ." From the wording of 37 C.F.R. § 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

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16. Instructions as to Overpayment

NOTE: "... Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

- ☒ Credit Account No. 10-1213
☐ Refund

00637923-1081400

Reg. No. 26,600

Tel. No. (703) 415-1500

Customer No.

 8/14/00
SIGNATURE OF PRACTITIONER

Douglas R. Hanscom

(type or print name of attorney)

JONES, TULLAR & COOPER, P.C.

P.O. Address

P.O. Box 2266 Eads Station
Arlington, Virginia 22202

☒ **Incorporation by reference of added pages**

(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)

- ☒ Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Number of pages added 5

- ☐ Plus Added Pages for Papers Referred to in Item 4 Above

Number of pages added _____

- ☐ Plus added pages deleting names of inventor(s) named in prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application.

Number of pages added _____

- ☐ Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added _____

☐ **Statement Where No Further Pages Added**

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item)

- ☐ This transmittal ends with this page.

ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

NOTE: See 37 CFR 1.78.

17. Relate Back

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

(complete the following, if applicable)

☒ Amend the specification by inserting, before the first line, the following sentence:

A. 35 U.S.C. 119(e)

NOTE: "Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number)." 37 C.F.R. § 1.78(a)(4).

☐ "This application claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:

FILING DATE

_____/_____
_____/_____
_____/_____

_____"
_____"

B. 35 U.S.C. 120, 121 and 365(c)

NOTE: "Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. . . . Cross-references to other related applications may be made when appropriate." (See § 1.14(a)). 37 C.F.R. § 1.78(a)(2).

- ☒ "This application is a
☐ continuation
☐ continuation-in-part
☒ divisional

of copending application(s)

- ☒ application number 08 / 904,175 filed on July 31, 1997"
☐ International Application _____ filed on _____
_____ and which designated the U.S."

NOTE: The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

NOTE: The deadline for entering the national phase in the U.S. for an international application was clarified in the Notice of April 28, 1987 (1079 O.G. 32 to 46) as follows:

"The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of § 1.494 and paragraph (i) of § 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the International application."

- ☐ "The nonprovisional application designated above, namely application _____ / _____, filed _____, claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:

FILING DATE

_____ / _____	_____ "
_____ / _____	_____ "
_____ / _____	_____ "

- ☐ Where more than one reference is made above, please combine all references into one sentence.

18. Relate Back—35 U.S.C. 119 Priority Claim for Prior Application

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in Item 17B, in turn itself claim(s) foreign priority(ies) as follows:

Country	Appln. no.	Filed on
---------	------------	----------

The certified copy(ies) has (have)

- ☐ been filed on _____, in prior application 0 / _____, which was filed on _____.
- ☐ is (are) attached.

WARNING: The certified copy of the priority application that may have been communicated to the PTO by the International Bureau may **not** be relied on without any need to file a certified copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore, such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications that have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).

19. Maintenance of Copendency of Prior Application

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).

- A.** ☐ Extension of time in prior application

(This item **must** be completed and the papers filed in the prior application, if the period set in the prior application has run.)

- ☐ A petition, fee and response extends the term in the pending **prior** application until _____
- ☐ A **copy** of the petition filed in prior application is attached.

- B.** ☐ Conditional Petition for Extension of Time In Prior Application

(complete this item, if previous item not applicable)

- ☐ A conditional petition for extension of time is being filed in the pending **prior** application.
- ☐ A **copy** of the conditional petition filed in the prior application is attached.

20. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

(complete applicable item (a), (b) and/or (c) below)

- (a) ☒ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are
- ☒ the same.
- ☐ less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:

(type name(s) of inventor(s) to be deleted)

- (b) ☐ This application discloses and claims additional disclosure by amendment and a new declaration or oath is being filed. With respect to the prior application, the inventor(s) in this application are
- ☐ the same.
- ☐ the following additional inventor(s) have been added:

(type name(s) of inventor(s) to be added)

- (c) The inventorship for all the claims in this application are
- ☐ the same.
- ☐ not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made
- ☐ is submitted.
- ☐ will be submitted.

21. **Abandonment of Prior Application** (if applicable)

- ☐ Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation-in-part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

22. **Petition for Suspension of Prosecution for the Time Necessary to File an Amendment**

WARNING: "The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." MPEP, § 706.07(b), 6th ed., rev.2.

NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.

(check the next item, if applicable)

- ☐ There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

23. **Small Entity** (37 CFR § 1.28(a))

- ☒ Applicant has established small entity status by the filing of a statement in parent application 08/904,175 on _____.
- ☐ A copy of the statement previously filed is included.

WARNING: See 37 CFR § 1.28(a).

24. **NOTIFICATION IN PARENT APPLICATION OF THIS FILING**

- ☒ A notification of the filing of this (check one of the following)
- ☐ continuation
- ☐ continuation-in-part
- ☒ divisional

is being filed in the parent application, from which this application claims priority under 35 U.S.C. § 120.

Practitioner's Docket No. _____

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: ROBERT BRUCE SPERTELL

Serial No.: 08 / 904,175

Group No.: 3736

Filed: July 31, 1997

Examiner: Ryan Carter

For: METHOD AND APPARATUS FOR TREATING SUBCUTANEOUS HISTOLOGICAL FEATURES

Assistant Commissioner for Patents
Washington, D.C. 20231

10511 U.S. PTO
09/637923



NOTIFICATION OF FILING OF CONTINUING,
DIVISIONAL OR CONTINUED PROSECUTION APPLICATION

Notification is hereby being made of the filing of a:

- ☐ continuation
☐ continuation-in-part
☒ divisional
☐ continued prosecution

application for this case

- ☒ concurrently herewith.

☐ on _____ Date

CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10

(When using Express Mail, the Express Mail label number is mandatory;
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I hereby certify that, on the date shown below, this correspondence is being:

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- ☐ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231
37 CFR 1.8(a)
☐ with sufficient postage as first class mail. ☐ as "Express Mail Post Office to Addressee"
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37 CFR 1.10*

TRANSMISSION

- ☐ transmitted by facsimile to the Patent and Trademark Office.

Signature _____

Date: _____

(type or print name of person certifying)

*WARNING: Each paper or fee filed by Express Mail **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Notification of Filing of Continuing, Divisional or Continued Prosecution Application [4-9] (page 1 of 2))

Reg. No. 26,6000

Tel. No.: (703) 415-1500

Customer No.:


SIGNATURE OF PRACTITIONER

8/14/00

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METHOD AND APPARATUS FOR TREATING SUBCUTANEOUS HISTOLOGICAL FEATURES

FIELD OF THE INVENTION

This invention relates to effecting pathological changes in subcutaneous histological features so as to eliminate unsightly or potentially harmful vascular and cellular conditions, without side effects and with fewer steps and less discomfort than has heretofore been possible.

BACKGROUND OF THE INVENTION

Radiation therapy is an accepted treatment for a wide variety of medical conditions. High intensity radiant energy sources in the visible band, such as lasers, are now being widely used for both internal and extracorporeal procedures. While the microwave band, between 300 MHz and 30 GHz affords the capability of penetrating deeper than visible light while interacting differently with body tissue it has heretofore been employed primarily only in a variety of dissimilar medical procedures.

Microwave energy exerts its effect on tissue through controlled regional heating (hyperthermia) of affected features through interaction between the wave energy and magnetically polarizable tissue matter. By using microwaves to establish a regional hyperthermia, it is possible to preferentially increase the temperature of diseased or unwanted histological features to levels which are pathologically effective. At the same time, a necessary objective is to maintain adjacent tissue at acceptable temperatures, i.e., below the temperature at which irreversible tissue destruction occurs. Such microwave induced hyperthermia is well known in the field of radiology where it is used in the treatment of individuals with cancerous tumors.

A number of specific methods for treating histological features by the application of microwave radiation are described in the medical literature. For example, a technique for treating brain tumors by microwave energy is disclosed in an article entitled "Resection of Meningiomas with Implantable Microwave Coagulation" in Bioelectromagnetics, 17 (1996), 85-88. In this technique, a hole is drilled into the skull and a catheter is invasively inserted into the hole to support a coaxial radiator or antenna. Microwave energy is then applied to the antenna to cause the brain tumor to be heated to the point where the center of the tumor shows coagulative necrosis, an effect which allows the meningioma to be removed with

minimal blood loss. Another technique in which microwave energy is utilized to treat prostate conditions is disclosed by Hascoet et al in U.S. Patent No. 5,234,004. In this technique, a microwave antenna in a urethral probe connected to an external microwave generating device generates microwaves at a frequency and power effective to heat the tissues to a predetermined temperature for a period of time sufficient to induce localized necrosis. In a related technique disclosed by Langberg in U.S. Patent No. 4,945,912, microwave energy is used to effect cardiac ablation as a means of treating ventricular tachycardia. Here, a radiofrequency heating applicator located at the distal end of a coaxial line catheter hyperthermically ablates the cardiac tissue responsible for ventricular tachycardia. As with the described methods of tumor treatment, this method of cardiac ablation operates by preferentially heating and destroying a specifically targeted area of tissue while leaving surrounding tissue intact.

While the general principle of propagating microwave energy into tissue for some therapeutic effect is thus known, such applications are usually based on omnidirectional broadcasting of energy with substantial power levels. The potential of microwave energy for use with subcutaneous venous conditions and skin disorders has not been addressed in similar detail, probably because of a number of conflicting requirements as to efficacy, safety, ease of administration and side effects.

As a significant number of individuals suffer from some type of subcutaneous but visible abnormality, therapeutic techniques which effectively address these conditions can be of great value. Such features which are potentially treatable by microwave energy include conditions such as excessive hair growth, telangiectasia (spider veins) and pigmented lesions such as café-au-lait spots and port wine stains (capillary hemangiomas). Of these conditions, excessive hair growth and spider veins are by far the most common, affecting a large percentage of the adult population.

Unwanted hair growth may be caused by a number of factors including a genetic predisposition in the individual, endocrinologic diseases such as hypertrichosis and androgen-influenced hirsutism as well as certain types of malignancies. Individuals suffering from facial hirsutism can be burdened to an extent that interferes with both social and professional activities and causes a great amount of distress. Consequently, methods and devices for treating unwanted hair and other subcutaneous histological features in a manner that effects a permanent pathological change are very desirable.

Traditional treatments for excessive hair growth such as depilatory solutions, waxing and electrolysis suffer from a number of drawbacks. Depilatory solutions are impermanent, requiring repeated applications that may not be appropriate for sensitive skin. Although wax epilation is a generally safe technique, it too is impermanent and requires repetitive, often painful repeat treatments. In addition, wax epilation has been reported to result in severe folliculitis, followed by permanent keloid scars. While electrolysis satisfactorily removes hair from individuals with static hair growth, this method of targeting individual hairs is both painful and time consuming. In addition, proper electrolysis techniques are demanding, requiring both accurate needle insertion and appropriate intensities and duration. As with wax epilation, if electrolysis techniques are not performed properly, folliculitis and scarring may result.

Recently developed depilatory techniques, utilizing high intensity broad band lights, lasers or photochemical expedients, also suffer from a number of shortcomings. In most of these procedures, the skin is illuminated with light at sufficient intensity and duration to kill the follicles or the skin tissue feeding the hair. The impinging light targets the skin as well as the hair follicles, and can burn the skin, causing discomfort and the potential for scarring. Further, laser and other treatments are not necessarily permanent and may require repeated applications to effect a lasting depilation.

Like hair follicles, spider veins are subcutaneous features. They exist as small capillary flow paths, largely lateral to the skin surface, which have been somewhat engorged by excessive pressure, producing the characteristic venous patterns visible at the skin surface. Apart from the unsightly cosmetic aspect, telangiectasia can further have more serious medical implications. Therefore, methods and devices for treating spider veins and other subcutaneous histological features in a manner that effects a permanent pathological change to the appropriate tissues are highly desirable.

The classical treatment for spider veins is sclerotherapy, wherein an injection needle is used to infuse at least a part of the vessel with a sclerotic solution that causes blood coagulation, and blockage of the blood path. With time, the spider veins disappear as the blood flow finds other capillary paths. Since there can be a multitude of spider veins to be treated over a substantial area, this procedure is time-consuming, tedious, and often painful. It also is of uncertain effectiveness in any given application and requires a substantial delay before results can be observed.

Another procedure for the treatment of shallow visible veins, which is similar to techniques used in depilation, involves the application of intense light energy for a brief interval. This technique exposes the skin surface and underlying tissue to concentrated wave energy, heating the vein structure to a level at which thermocoagulation occurs. In particular, these energy levels are so high that they cause discomfort to some patients, and they can also be dangerous to those in the vicinity, unless special precautions are taken. In addition, some patients can be singed or burned, even though the exposure lasts only a fraction of a second.

Due to the serious problems that the subcutaneous abnormalities can create in individuals, there is a general need to be able to treat such features in a manner that effects beneficial pathological change without adverse side effects or discomfort. An optimal therapeutic technique should effect a permanent pathological change without requiring repeated applications to reach the desired effect. Moreover, these procedures should be noninvasive, should cover a substantial target area that is not limited to a single hair follicle or spider vein, and should make optimum use of the energy available. Finally, pathological changes should occur only in the targeted feature, and not in intervening or underlying layers.

SUMMARY OF THE INVENTION

The present invention overcomes the deficiencies in previously described methods for treating subcutaneous features by delivering a dosage of microwave energy that is maintained for only a short duration but at an energy level and at a wavelength chosen to penetrate to the depth of a chosen histological feature. The subcutaneous features are destroyed or pathologically altered in a permanent fashion by the hyperthermic effect of the wave energy while the surrounding tissue is left intact.

In accordance with the invention, the effective delivery of microwave energy into the subcutaneous feature can be maximized in terms of both the percentage of energy transmitted into the body and a preferential interaction with the target feature itself. The microwave energy is specifically targeted to the chosen depth and the targeted feature is heated internally to in excess of about 55°C, to a level which thromboses blood vessels and destroys hair follicles. The ability to target a wide area containing a number of features simultaneously enables a single procedure to supplant or reduce the need for repetitive applications.

Methods in accordance with the invention utilize certain realizations and discoveries that have not heretofore been appreciated in relation to wave energy-tissue interactions at a substantial depth (up to 5 mm below the skin surface). The wavelengths that are selected are preferentially absorbed by a targeted feature such as a blood vessel more readily than by skin surface and tissue. Thus, a chosen frequency, such as 14 GHz, penetrates through surface tissue to the chosen depth of the target feature, but not significantly beyond, and the energy heats the target more than adjacent tissue. Dynamic thermal characteristics are also taken into account, because transfer of thermal energy from small target features such as minute heated blood vessels to the surrounding tissue (the "thermal relaxation time") is much faster than that for larger vessels. The duration of a dosage, typically in the range of 100 milliseconds, is varied to adjust for this size factor.

Immediately prior to, concurrently with, or after the application of penetrating microwave energy, the skin surface is advantageously cooled. This cooling may be effected in a number of ways such as through the delivery, as rapidly expanding gas, of known coolants into a small space between the microwave emitter and the skin surface. The use of coolant enables the surgeon not only to minimize patient discomfort and irritation, but also to adjust energy dosages in terms of intensity and duration, because heat extraction at the surface also affects heating to some depth below the surface. The surgeon can also employ air cooling to minimize irritation while assuring results over a larger subcutaneous area and with fewer applications.

While it is advantageous to cool the skin surface with a separate medium in the target area immediately prior to or during wave energy application, it is also shown that the wave energy emitting device itself can be used to draw thermal energy off the skin surface. Again, the skin is heated minimally, giving the patient little, if any discomfort, and avoiding skin irritation. Comfort may be ensured for sensitive patients by a topical anesthetic, or by a conductive gel or other wave energy complementary substance introduced between the applicator and the skin surface.

The energy applied is generally in excess of about 10 Joules, and the duration is typically in the range of 10 to 1,000 milliseconds, with about 100 milliseconds being most used. The total energy delivered is typically in the range of 10-30 Joules, although the energy delivered as well as frequency may be changed in accordance with the nature of the targeted features, the target volume and depth. In a depilation process, for example, 10 to 20 Joules will usually suffice

when a compact applicator is used, while a higher input level, such as 20 to 30 Joules, is used for a telangiectasia treatment.

5 A system in accordance with the invention for use in such procedures may employ a tunable power generator, such as a tunable power source operable in the microwave range from 2.45 GHz to 18 GHz, and means for gating or otherwise
10 controlling the power output to provide selected pulse durations and energy outputs. The system also can incorporate power measurement sensors for both forward power and reflected power or circuits for measuring impedance directly. Thereby, tuning adjustments can be made to minimize reflection. Power is delivered through a manipulatable line, such as a flexible waveguide or coaxial line, to a small and conveniently positionable applicator head which serves as the microwave launcher or emitter. The applicator head may advantageously include, in the wave launching section, a dielectric insert configured to reduce the applicator cross-section, and to provide a better match to the impedance of the skin
15 surface. Furthermore, the dielectric insert is chosen so as to distribute the microwave energy with more uniform intensity across the entire cross section, thus eliminating hot spots and covering a larger area.

If the dielectric is of a material, such as boron nitride or beryllium oxide, which is a good thermal conductor, it can be placed in contact with the skin and
20 thermal energy can be conducted away from the skin as microwave energy is transferred. Different clinical needs can be met by making available a number of different dielectric element geometries fitting within an interchangeable mount. The applicator head may further include a pressure limiting mechanism to insure that the head does not compress vessels as the procedure is being carried out.

25 In addition to the range of capabilities thus afforded, the surgeon can use ultrasound or other inspection techniques to identify the locations of the subcutaneous features for the precise mapping of target sites. Using an indexing or aiming device or element on the applicator head, energy can be applied a minimum number of times at precise locations to encompass a maximum number of targets.
30 Because skin and tissue characteristics vary, pretesting target characteristics and varying the frequency or phase applied can increase efficiency and reduce the possibility of side effects.

In another application in accordance with the invention, the skin target area may be more readily visualized by using a microwave launcher positionable within
35 an end unit in one of two alternate positions. In one position, the target area can be viewed and the launcher indexed for movement into precise proximity to the target

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area. In yet another example, a rectangular waveguide of standard size and therefore larger cross-section is used, with air cooling of the skin surface. For depilation, a peel-off, attachable label locating a number of delineated contiguous target areas can be placed on the skin. When the applicator has been energized at each target area, the label sheet can be peeled off, removing hair residue with it.

The applications of the process and method are not limited to conditions such as spider veins and unwanted hair, but further encompass pigmented lesions and related abnormalities, as well as other temporary and permanent skin disorders.

BRIEF DESCRIPTION OF THE DRAWINGS

A better understanding of the invention may be had by reference to the following specification, taken in conjunction with the accompanying drawings, in which:

Fig. 1 is a combined block diagram and perspective view of a system in accordance with the invention;

Fig. 2 is a side view, partially in section, of a microwave applicator for use in the system of Fig. 1;

Fig. 3 is a fragmentary view of the beam launching end of a microwave applicator in relation to a graphical representation of electric field strength across the applicator;

Fig. 4 is a simplified, perspective view of a section of subcutaneous structure, depicting different layers therein in relation to blood vessels and hair follicles;

Fig. 5 is an enlarged sectional view of a hair structure from root to shaft;

Fig. 6 is a simplified depiction of method steps in accordance with the invention;

Fig. 7 is a graphical depiction of loss factor curves showing the comparative absorption of microwaves in blood and tissue at different frequencies;

Fig. 8 is a graphical depiction of the temperature changes at and below the skin surface during practice of methods in accordance with the invention;

Fig. 9 is a graphical depiction of the variation in thermal relaxation time for different blood vessel diameters;

Fig. 10 is a simplified perspective view of a different microwave applicator used in conjunction with a removable positioning sheet; and

Fig. 11 is a perspective, partially broken away, view of an alternative applicator head including internal cooling and a viewing system.

DETAILED DESCRIPTION OF THE INVENTION

A system in accordance with the invention, referring now to Fig. 1, is depicted in an example intended for use in hair removal, the treatment of spider veins and other skin disorders. This configuration includes a hand-held applicator that is suitable for potential use at any frequency within a suitable range, as well as for measurement of skin or tissue properties. Such a system can be used for treating any of a variety of skin disorders, including hirsutism, telangiectasia, pigmented lesions and the like. It will be apparent to those skilled in the art that where such degrees of versatility and usage in different possible applications are not required, a simpler and less expensive system will often suffice. In addition, if a manually moveable applicator head is not required, the system can be simplified in this respect as well. In the most rudimentary example, a monofrequency unit with means for adjusting dosage driving a fixed applicator head may be adequate.

Referring to Fig. 1, in a system 10 in accordance with the invention microwave energy of a selected frequency can be generated by any one of a number of conventional devices, such as a variable frequency synthesizer 14 that covers a range from about 2 GHz to about 20 GHz. A number of other conventional microwave generators are tunable in the range of 2.45 GHz to 18 GHz, for example, but here a suitable combination includes the frequency synthesizer 14 and a traveling wave tube system 12 having internal power and a high power output amplifier. Where operating conditions are well-defined and wide tunability is not needed, a conventional low cost source such as a magnetron may be used. The output of the traveling wave tube system 12 is gated open for selected intervals by control pulse circuits 16, which can be set, in this example, for any interval from 10 to 1000 milliseconds. Thus, the selected frequency is delivered as a pulse burst to provide from 50W to as much as 4KW output, the power level most often being of the order of a few hundred watts. In transmission to the operative site, the power bursts are directed through a power sensor 18, which diverts both forward and reverse propagated energy samples to a power meter 20. Readings at the power meter 20 enable the surgeon to fine tune power, phase or frequency settings to improve impedance matching and energy efficiency.

Preinspection of the target site is dependent on the nature of the target. Although visual inspection is sometimes alone sufficient for target area selection, as with hirsutism, target veins at depth below the surface can often better be identified, located, and dimensioned by conventional analytical instruments, such

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as those using ultrasound imaging. As is described hereafter, the power, duration and frequency applied can also be adjusted in relation to the thermal relaxation characteristics of a target blood vessel, which in turn is dependent on size and location.

5 A microwave transmission line 24, here including a flexible rectangular waveguide or a flexible coaxial section 26 that may be manually manipulated, supplies the microwave energy through a phase shifter or other kind of tuner 27 to a hand applicator 30 shown here as positioned against a limb 32 exposed within a surgical drape 34. The handpiece 30, shown in greater detail in Figs. 2 and 3, is
 10 essentially a rectangular waveguide device having a stepped or other impedance matching section 36 coupled to the flexible coaxial line 26. The handpiece 30 includes a converging tapered body 38 having an open aperture end 40 serving as the wave launching terminus. Internal to the tapered waveguide section 38 is a dielectric insert 44 here formed of two high dielectric ($K = 16$) tapered strips 46, 47
 15 held in place between low dielectric constant ($K = 2.5$) spacers 48 of a virtually microwave transparent material such as "Rexolite". This configuration of dielectrics, as seen in Fig. 3, spreads the electric field distribution toward the sidewalls, enlarging the target area that is effectively acted upon by the wave energy and eliminating any hot spot tendency within the target area. In addition,
 20 the dielectric insert 44 provides a better impedance match to the skin, reducing reflective losses, which can further be minimized by adjustments at the tuner 27. The dielectric 44 also reduces the cross-sectional area and size of the waveguide, thereby making the handpiece 30 easier to handle. In addition, the internal taper matches the waveguide impedance to the different impedance of the dielectric
 25 loaded section, so as to minimize reflection.

The flexible coaxial line 26 allows a surgeon to move the applicator 30 to place its open end manually wherever desired on the body surface 32. At the frequency range of 12-18 GHz, a standard WR 62 waveguide section with 0.622" x 0.311" orthogonal dimensions can be employed at the output end of the
 30 impedance matching section 36. The tapered section 38, loaded by the dielectric 44 in this example, reduces the waveguide dimension to 0.250" x 0.150" at the output terminal face 40. The end face 40, however, is set off from the limb or other body surface 32 against which it is juxtaposed by an encompassing and intervening spacer element 54, best seen in Figs. 2 and 3. The spacer element 54
 35 includes an interior shoulder 56 extending around the periphery of the end 40 of the tapered section 38, defining a standoff volume of a height of about 0.020" (0.5

mm). A coolant can thus be injected via a side conduit 58 from a pressurized coolant gas source 60 (Fig. 1), via a coupling conduit 62 extending through a solenoid controlled valve 64. The pulse control 16 opens the valve 64 in timed relation to the microwave pulse to be delivered from the traveling wave tube system 12. This timing relation can be controlled, so that the target skin area can be precooled prior to delivery of the microwave pulse, cooled concurrently with the delivery or cooled after the start of the delivery of the microwave pulse. Furthermore, a temperature sensor 68, shown only generally in Fig. 1, may be disposed within the standoff volume, in contact with the skin or otherwise, to sense the lowering of temperature at the target surface. In this example, the coolant is a pressured gas, such as 1,1,1,2 tetrafluoroethane, held under high pressure in liquefied or gaseous phase. When injected by actuation of the valve 64, the gas expands vigorously within the standoff volume, rapidly lowering the temperature because of the expansion effect. Since the boiling point of the tetrafluoroethane is approximately -26°C at 1 atm, it is extremely effective in extracting thermal energy from the target area, even for the short bursts of the order of a fraction of a second that are involved in the present procedure. The temperature sensor 58 may be a Luxtron fiber optic device for measuring temperature, or it may be a thermistor which is coupled in a circuit that triggers the microwave pulse when the coolant has adequately lowered the temperature at the skin surface or in the standoff volume. Other coolants, including air, can alternatively be used to reduce the skin surface temperature within the standoff volume during the procedure.

Other alternative approaches may be utilized to minimize discomfort and, separately or additionally, provide improved efficiency. A compound that is complementary to the delivery of the microwave energy, in the sense of neither being reflective or absorptive, and therefore not appreciably heated, can be placed on the skin prior to microwave pulse application. For example, a topical anesthetic having short term effectivity may be all that is needed to reduce the discomfort of some patients to an acceptable level. Other patients may require no coolant or topical anesthetic whatsoever. Another alternative is to employ a surface gel or other substance that improves impedance matching between the microwave pulse launching device and the surface tissues.

The microwave delivery system provided by the applicator 30 delivers microwave energy over an advantageously broad field distribution into a subcutaneous surface area as best understood by reference to Fig. 3. The dielectric loading introduced by the spaced apart dielectric elements 46, 47, which diverge

toward the output end as the sidewalls converge in the tapered section 38, alters the normal horizontal electric field distribution from its normal half sine wave characteristic so that there is substantial field strength at the two sidewalls and no high central energy peak. A single, appropriately shaped, dielectric element can be used to modify the field distribution to like effect. By thus spreading the energy across the target area, there is both elimination of localized energy concentrations (and therefore localized heating) and a larger effective treatment area. As seen in the graphical portion of Fig. 3, in the solid line, the calculated electric field at the skin surface when the outlet end 40 of the microwave launcher is 0.5 mm off the surface, is more than twice that at the edges. This differential is reduced when the field distribution is modeled at a depth of 0.5 mm below the skin surface. In both instances, there is a degree of dispersion outside the perimeter of the applicator face 40 because of the setoff spacing, but this aids in equalizing the power distribution and poses no radiation danger.

In accordance with the present invention, advantage is taken of the results of an analysis of the interaction of microwaves with biological tissues at different frequencies. The complex permittivity ϵ^* of any given matter, including biological matter, in a steady state field is conventionally analyzed using the following equation:

$$\epsilon^* = \epsilon_0 (\epsilon' - j\epsilon''),$$

in which ϵ_0 is the dielectric constant of free space and the real component, ϵ' , is the dielectric constant, while the imaginary component, ϵ'' is the loss factor. As seen in Fig. 7, the loss factor (ϵ'') of blood, in the range of 2 to 20 GHz, shown by tests to be substantially higher than that of skin tissue. Further analysis has ascertained that by considering both relative and absolute factors, the most advantageous conditions exist at about 14 GHz. From published work, the dielectric constant of skin is known to be about 22 at 10 GHz and to decrease with increasing frequency to a value of 12 at 18 GHz. The loss factor for skin reaches a peak of 18 at 9 GHz and decreases with increasing frequency to a value of 12 at 14 GHz. The loss factor ϵ'' for skin is approximately one-half that for blood in the frequency range between 14 GHz and 20 GHz, and above 10 GHz the loss factor for blood increases somewhat more than for skin, as seen in Fig. 7. Therefore, the heat generated per unit volume in blood and to some extent in differentiable cellular structures other than skin, can be expected to be twice that of skin. Consequently, differential heating results when microwave energy penetrates subcutaneous regions. Because these subcutaneous regions are of depths up to 5 mm, they are

directly within the range of interest that includes hair follicles and roots, telangiectasia, pigmented lesions, and other histological features that are visible through the epidermis and/or dermis, or actually protrude at the skin.

The structure of skin is somewhat idealistically and simplistically depicted in Fig. 4, in order to show the physical relation and relative proportions (although not to scale) between the epidermis and dermis layers that lie above subcutaneous tissue, and to further represent histological features of interest in the structure. Sweat glands, nerve endings, corpuscular structures and sebaceous glands are not included for clarity. The hair shafts, most deeply embedded at their roots at 4 to 5 mm depth in the dermis, extend outwardly through the dermis and the relatively more robust epidermal layer. Relatively large arteries and veins branch into the arteriole and venule vessels which feed and derive blood, respectively, as the smallest capillaries that normally are invisible from the skin surface, and that form the termini of the blood paths. When these capillaries, either or both arterioles and venules, become engorged for some reason, as in the telangiectasia condition, they form the lateral and visible pattern, known collectively as spider veins, at a depth of 0.1 to 1.0 mm below the surface of the epidermis. Typically of the order of 0.2 mm in diameter, the spider veins can actually sometimes protrude at the surface, and be larger in diameter as well. Reticular or feeder veins can lie as much as 5 mm in depth below the surface, and are substantially larger, of the order of 1.0 to 2.0 mm in diameter, being large enough to be identified by a non-invasive inspection technique, such as imaging with ultrasound. The reticular or feeder veins sometimes create the overpressure condition causing engorgement of the spider veins.

Fig. 5 shows further details, again somewhat idealized, of an enlarged hair shaft, extending outwardly from a root into the growing cellular structure of the follicle and the follicle casing that transforms into the hair shaft body that passes through the epidermis. The hair follicle is nourished by at least one artery that feeds the papillae structure at the root and is encompassed in a crown of associated matrix cells. Attack on the cellular follicle structure or on the papillae or the arterioles or venules to and from the papillae can result in permanent destruction of the hair shaft.

With these considerations in mind, appreciation of the operation of the system of Fig. 1 can more readily be gained. The surgeon can use a suitable frequency for a chosen histological feature within the range of the frequency synthesizer 14. It is assumed here that the frequency chosen is about 14 GHz. The

traveling wave tube system 12 is set to generate approximately 100 to 300 watts, the control pulse circuits 16 being set to open the solenoid valve 64 prior to getting a short pulse from the microwave system 12. It has been found that a 100 millisecond pulse is satisfactory for both efficacy and safety, although other durations can be used with wattage adjustments to compensate. The output from the traveling wave tube system 12 is directed through the power sensor 18, the transmission line 24, the flexible section 26, through the tuner 27 and to the applicator 30. If the operator desires, short test pulses of low amplitude can first be sent to obtain readings of the reflected power at the power meter 20, and fine tuning adjustments can be made at the tuner 27, in a conventional manner. In addition, the operator can use ultrasound or another non-invasive diagnostic system to analyze the substructure to identify the position of target features, such as reticular veins and arteries, both as to size and location. The procedure initially to be described, however, pertains to depilation, so that the target area is not only readily visible, but is also substantially uniform in depth and structure, as per Fig. 5.

When the control pulse circuits 16 operate, they first provide a control impulse to open the solenoid valve 64, in this example, and then turn on the traveling wave tube system 12 for the selected interval. Because the valve requires a few milliseconds (e.g., 20 to 35) to operate and a few milliseconds are also needed for the pressurized coolant from the source 60 to pass through the outer conduit 62 and the side conduit 58 in the spacer 54, it is preferred to delay the microwave pulse until cooling has actually begun or is contemporaneously begun. Alternatively, as previously noted, a temperature sensor 68 that detects a temperature drop at the skin surface may be used to either trigger the microwave pulse or to preclude its operation until after the coolant has become effective.

For depilation, pulses in the range of 10 to 20 Joules in terms of total work output have been shown to effect permanent depilation without significant discomfort or significant adverse side effects. Tests were run using the dielectric loaded applicator 30 having a 0.250" x 0.150" output area (5 mm x 3 mm, or 15 mm²), and employing a pulse duration of 100 milliseconds in all instances. A substantial number of experiments were run on test rabbits with this applicator, varying only the power applied so as to change the total energy in Joules. The results were examined by a pathologist and the accompanying Tables 1 and 2, appended following the specification, show the results of his examination.

The system of Fig. 1 was also employed in a number of tests on rabbits to determine the changes occurring in veins and arteries under different pathological changes, and side effects on tissues and vessels with a protocol using cooling as well as no cooling to determine if pigmentation has an effect are shown in appended Table 3. These tests showed no significant difference in pigmentation versus non-pigmentation, indicating that coloration, and/or the presence of melanin, is not a significant factor in absorption of microwave energy. A different protocol was followed in amassing results shown in appended Table 4, which represents an analysis by a pathologist blinded to the dosages used. Cooling was not used in this example. These results with test rabbits show that pigmentation is not a significant factor and that at 16 Joules dosage and above, there is effective occlusion of target veins and arteries with minimal changes or only mild induration of tissues. The indication of dermal fibrosis again is not indicative of scar development.

Pathological examination of these animal studies consistently demonstrated destruction of hair follicles over a wide range of microwave energy levels. The destruction extended to the base of the follicle, which is significant to permanent hair removal. The amount of hair destruction within the target area varies in accordance with the total amount of energy, but destruction is substantially complete at 14 Joules and higher. Furthermore, until the energy delivered is in excess of 20 Joules, the appearance of the skin is normal in all cases and the epidermis is histologically intact. Minor indications of dermal fibrosis are not indicative of clinical scar formation. Minor vascular changes, such as intimal fibrosis of small arteries, constitute neither damaging nor permanent conditions. Consequently, a dosage in the range of 14 to 20 Joules is found both to be effective and to be free of deleterious side effects.

The effects of delivery of microwave energy, with surface cooling, are illustrated graphically in Fig. 8, which indicates temperature changes at both the surface of animal skin tissue (0.75 mm thick) and 1.5 mm below the surface, in water, under conditions of delivery of up to 12 Joules total energy level over 100 milliseconds duration, accompanied by cooling using expanded tetrafluoroethane gas. As shown, the baseline temperature for the test animal skin is approximately 32°C, and that for the body at a depth of 1.5 mm is approximately 37°C. Applying the microwave energy with cooling, the skin surface temperature rose very slightly, but was essentially unchanged. Beneath the skin surface, however, the temperature rise at 1.5 mm depth was at a substantially higher rate, reaching approximately

60°C at 100 milliseconds. Higher temperatures would of course be reached with the application of higher energy levels. It is posited that even such a temperature is sufficient to cause cellular degradation of the hair follicles near the root, and it may well also thermocoagulate blood in the feeder artery, in the papillae at the hair root, or in the cell matrix surrounding the papillae. Although the hair follicles are not conductive, they may be particularly susceptible to the impinging microwave energy because they are thin dielectric elements which can cause energy concentration and therefore greater heating. Whether one or more effects are observable, permanent destruction has been shown by pathological examination, as in the annexed tables.

The microwave energy does not significantly penetrate beyond the depth of the targeted histological features because of attenuation, the limitation on total energy delivered and the lower loss factor in tissue.

Where the histological defects are benign vascular lesions, as with the telangiectasia condition, different tests and operating conditions may be employed, as shown in the steps of Fig. 6, to which reference is now made. While spider veins can cover a substantial area, and visual targeting may be sufficient, it is often desirable to analyze the target area in greater detail. Thus, ultrasound examination may be utilized to identify and estimate the size of reticular veins feeding a substantial area of spider veins, as an optional first step 80, which can precede marking of the target surface 82 in any appropriate way. Again, the dielectric constant, skin impedance or other characteristics may be tested in a preliminary step 84, prior to choosing operative frequency in step 86. Fine tuning, phase adjustment or another impedance matching option 88 may be employed to reduce reflective losses and increase efficiency. Given the size and location of the target vascular feature, thereafter, the power level and pulse duration may be selected in a step 90.

The pulse duration is a significant parameter in relation to the vessel diameter, since the smaller the vessel diameter, the shorter is the thermal relaxation time. Even though the loss factor of blood is higher than that of the tissue, dissipation of heat to surrounding tissue is much faster with a small blood vessel and consequently shorter term heating is needed. As seen in Fig. 9, thermal relaxation time increases monotonically with vessel diameter, and thus a longer duration pulse is needed, perhaps at the same or a greater power, if the vessel diameter is of a larger size. Given the power level and pulse duration, the operator can select one of the cooling options, which also includes no cooling whatsoever,

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in step 92. Typical anesthetics or other anesthetics may be employed at the same time, as shown by optional step 94.

Consequently, when the microwave pulse is delivered, the subcutaneous target is heated to the range of 55°C to 70°C, sufficient to thrombose the vascular structure and terminate flow permanently. The specific nature contributing factors to disappearance of the vessels with time may be one or more factors, including thermocoagulation of the blood itself, heating of the blood to a level which causes thrombosis of the vessel or some other effect. The net result, however, is that a fibrous structure forms in the vessel which clogs and terminates flow, so that the resultant fibrous structure is reabsorbed with time, as new capillary flow paths are found. In any event, heating in the 55°C to 70°C is sufficient to effect (step 96) the permanent pathological change that is desired (step 98).

An alternative applicator that covers a larger area and is employed with a peelable indicia label as shown in Fig. 10. The standard WR 62 waveguide for transmission of microwave energy at 14 GHz has, as previously mentioned, interior dimensions of 0.622" x 0.311". An applicator 100 employing such a waveguide section 101 is used directly, without internal dielectric loading, to cover a substantially larger target area while employing air cooling. The waveguide section 101, coupled via a flexible waveguide and an impedance matching transition (not shown), if necessary, to a microwave feed system 102 has side wall ports 104 coupled to an external coolant source 105 which may deliver coolant through a control device 106 triggered, in relation to the microwave pulse, as previously described. Under some circumstances, when air is used as the coolant, it may simply be delivered continuously into the waveguide, the end of which can be blocked off by a microwave transmission window so that only the launching end and the skin surface are cooled. For use in a depilation procedure, the skin surface of a patient to be treated is covered with a sheet 108 having numbered guide indicia 109 for marking successive applicator 100 positions. These positions overlap because of the fact that the energy concentration is in the central region of the waveguide 101, at the normal maximum amplitude of the electric field in the TE₁₀ mode. The peel off label sheet 108 is covered on its skin-adhering side by a separable adhesive. Consequently, when the applicator 100 is moved between successive overlapping index positions marked 1,1,2,2 etc. at the side and corner of each position, the internal areas that are pathologically affected within each location are essentially contiguous, until the entire applicator 100 has been moved through all positions on the sheet 108, with dosages applied to all of the areas.

Hair follicles having been destroyed in those areas, the procedure is terminated and the sheet 108 is peeled off, with the destroyed hair follicles and shafts adhering to it.

- With the arrangement of Fig. 10, a longer microwave pulse duration or more wattage is needed for increasing the number of Joules because of the broader beam distribution, which means that heating is at a slower rate (e.g., in the approximate proportion of 0.7°C rise in skin temperature per joule for the large applicator versus 2.4°C per joule for the dielectric filled smaller applicator). The skin temperature rise was reduced by a factor of 2 when using air at a temperature of between 0°C and -5°C .

It should be noted, furthermore, that a standard open rectangular waveguide can be loaded with dielectric elements in a manner which enables size to be reduced without restricting coolant flow.

- Another alternative that may be used, but is not shown in the figures, relates to a modification of the spacer element that is employed in the example of Figs. 2 and 3. One can configure the spacer element with two alternative but adjacent positions for the applicator open (emitter) end, and arrange the applicator so that the emitter end can be shifted between the two positions. In a first or reserve position of the applicator, the target surface can be viewed through the spacer element, and positional adjustments can be made. This part of the spacer element is then used as a frame for visualizing the operative target on the skin surface when the applicator is in the reserve position. As soon as the target area is properly framed, the applicator is simply shifted from the reserve position to the operative position, in proper alignment with the target area, and the procedure can begin.

- A different approach to a useful applicator is shown in Fig. 11, to which reference is now made. This also illustrates a different means for cooling the skin surface, as well as for viewing the target area. In this example, the applicator 120 comprises an open-ended wave propagation segment 122 fed via a transition section 124 from a coaxial line 126. The unit may be physically manipulated by an attached handle 128. The open end of the waveguide 122 is filled by a dielectric element 130 which is not only of suitable electrical dielectric properties but a good heat conductor as well, such as boron nitride or beryllium oxide. The dielectric insert 130 extends beyond the open end of the waveguide, into contact with a skin surface that is to be exposed to microwave radiation. The interior end of the dielectric 130 is urged in the direction toward the skin surface by a non-conductive, non-absorptive microwave leaf spring 134 of selected force and

compliance. Thus, the dielectric insert 130 presses on the skin surface with a yieldable force, selected to assure that contact is maintained but that any protruding veins or arteries are not closed simply by the force of the applicator 120. This applicator 120 and dielectric insert 130 are externally cooled by an encompassing sleeve 136 through which coolant is passed via internal conduits 137, 138 that communicate with an external supply (not shown) via external conduits 141, 142. Consequently, heat is extracted from the surface of the skin via the contacting dielectric 130 itself.

In addition, a target mark placed on the skin surface by the surgeon may be viewed by a system including a fiber optic line 145 that extends through the dielectric 130 and leads via a flexible fiber optic line 147 to an image viewing system 149.

In use, this applicator 120 of Fig. 11 covers a substantial chosen area, with the viewing and cooling features that simplify placement and minimize discomfort. The movable dielectric insert 130 can be a replaceable element, with different shapes of dielectrics being submitted where different conditions apply. It will be appreciated that other expedients may be utilized for shaping the microwave beam, including lens and diffuser systems.

Although a number of forms and modifications in accordance with the invention have been described, it will be appreciated that the invention is not limited thereto, but encompasses all forms and expedients in accordance with the appended claims.

TABLE 1

ANIMAL STUDY PROTOCOL NP970305

Applicator Tip: 0.250" x 0.150"; Cooling

Rabbit	Dose (Joules)	Description of Skin	Histologic Description		
			Tissue	Hair Follicles	Vasculature
B9	13	skin intact; decreased density of hair	some fibrosis; mild edema	few hair follicles	vessels patent
B10	15.2	skin intact; decreased density of hair	dermal fibrosis	relative absence of hair follicles	vessels patent
B11	19.6	skin intact; decreased density of hair	normal	paucity of hair follicles	vessels patent

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TABLE 2

ANIMAL STUDY PROTOCOL NP970505

Applicator Tip: 0.250" x 0.150"; Cooling

Rabbit	Dose (Joules)	Description of Skin	Histologic Description		
			Tissue	Hair Follicles	Vasculature
B1/R	22.4	skin intact; hairless	tissue viable, dermal fibrosis	absent, squamous metaplasia	veins patent; arteries patent; increased intimal fibroblasts
B1/L	22.4	skin intact; hairless	tissue viable, dermal fibrosis	hair follicle destruction	veins patent, arteries patent, intimal fibrosis
B2/R	20.0	skin shiny; hairless	tissue viable, dermal fibrosis	hair follicle destruction	possible fibrous cord in small vein; arteries not seen in these sections
B2/L	20.0	skin intact, shiny and hairless	tissue viable, dermal fibrosis	hair follicle destruction	veins patent; arteries patent, increased intimal fibroblasts, mild edema
B3/R	24.1	skin shiny and hairless, fine granularity	tissue viable, dermal fibrosis, small area of necrosis on opposite side of ear (no cooling)	hair follicle destruction; squamous metaplasia	veins patent; arteries not seen in these sections
B3/L	23.6	three indurated areas, crusting of epidermis, hairless single punched out area	subacute granulation tissue	absence of hair follicles	vessels not seen in these sections

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TABLE 2

ANIMAL STUDY PROTOCOL NP970505

Applicator Tip: 0.250" x 0.150"; Cooling

Rabbit	Dose (Joules)	Description of Skin	Histologic Description		
			Tissue	Hair Follicles	Vasculature
B4/R	23.7	skin shiny and hairless; fine granularity	tissue viable, dermal fibrosis	absence of hair follicles	fibrous cord in small vein; arteries not seen in these sections
B4/L	23.6	four indurated areas	tissue viable, dermal fibrosis	hair follicle destruction	congestion of small caliber veins; intimal fibrosis, narrowing of small arteries
B5/R	20.7	skin intact; hairless	tissue viable, dermal fibrosis	absence of hair follicles, squamous metaplasia	vein possibly narrowed; arteries patent, intimal fibrosis
B5/L	21.4	skin intact, hairless, tiny hole	tissue viable, dermal fibrosis	absence of hair follicles	veins patent; arteries patent, intimal fibrosis
B6/R	22.0	skin intact, hairless, fine granularity	tissue viable, dermal fibrosis	absence of hair follicles, squamous metaplasia	veins patent; narrowed small artery with intimal fibrosis
B6/L	22.0	punched out area	dermal fibrosis	hair follicle destruction, squamous metaplasia	arteries and veins patent
B7/R	19.2	skin intact, hairless	minimally affected	focal area of hair follicle destruction	veins patent; partial thromboisis of small artery
B7/L	20.5	skin intact, hairless	dermal fibrosis	focal paucity of hair follicles, squamous metaplasia	veins patent; arteries patent, minimal intimal fibrosis

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TABLE 2

ANIMAL STUDY PROTOCOL NP970505

Applicator Tip: 0.250" x 0.150"; Cooling

Rabbit	Dose (Joules)	Description of Skin	Histologic Description		
			Tissue	Hair Follicles	Vasculature
B8/R	19.0	skin intact, hairless	focal areas of dermal fibrosis	focal destruction of hair follicles	veins patent; occlusion of small artery with fibrous cord
B8/L	21.4	skin intact, hairless	dermal fibrosis, small zone of nodular fibrosis	destruction of hair follicles	veins patent; arteries not seen in these sections
B9/R	23.0	skin intact, hairless	small zone of dermal fibrosis	relative absence of hair follicles, squamous metaplasia	veins patent; arteries patent
B9/L	23.0	skin intact, hairless	dermal fibrosis	destruction of hair follicles, squamous metaplasia	veins patent; arteries patent with mild intimal fibrosis
B10/R	24.6	skin intact, hairless	mild fibrosis	destruction of hair follicles	veins patent; arteries patent with mild intimal fibrosis
B10/L	24.7	skin intact, hairless	dermal fibrosis	destruction of hair follicles	veins patent; partial thrombosis of small artery
B11/R	22.4	skin intact, hairless	minimal changes	minimal changes	veins patent; arteries patent
B11/L	21.5	skin intact, hairless	dermal fibrosis	destruction of hair follicles, squamous metaplasia	veins patent; arteries patent
B12/R	20.6	skin intact, hairless	dermal fibrosis	destruction of hair follicles, squamous metaplasia, remnants of follicles seen	veins patent; arteries patent
B12/L	19.6	skin intact, hairless	zone of dermal fibrosis	destruction of hair follicles	veins patent; arteries patent

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TABLE 3
ANIMAL STUDY PROTOCOL NP970603
 Applicator Tip: 0.250" x 0.150"

Rabbit	Pigmented	Dose (Joules)	Cooling	Appearance of Skin
A1	No	5.3	No	skin intact – back and ear
			Yes	skin intact – back and ear
A2	Yes	5.6	No	skin intact – back and ear
			Yes	skin intact – back; tiny dot left ear
B1	No	9.4	No	back – minimal pallor 2/3 sites; skin on ear intact
			Yes	skin intact – back and ears
B2	Yes	9.3	No	skin on back obscured by hair growth; skin on ear intact
			Yes	skin on back obscured by hair growth; skin on ear intact
C1	No	14.3	No	back – slight abrasion 2/3 sites, small scab 3; skin on ear intact
			Yes	skin intact – back and ear
C2	Yes	14.8	No	skin on back obscured by hair growth; skin on ear intact
			Yes	skin on back obscured by hair growth; skin on ear intact
D1	No	18.4	No	back – scabs all 3 sites; ear – tiny scab
			Yes	back – slight pallor 2/3 sites, minimal change at site 3; ear – minimal change
D2	Yes	18.6	No	back – small, raised areas at all 3 sites; ear – small raised area
			Yes	skin intact – back and ear

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TABLE 4
ANIMAL STUDY PROTOCOL NP970208

No Cooling

Rabbit	Joules	Histology-Tissue	Histology-Vein	Histology-Artery	Clinical-Tissue	Clinical-Vessels
D1/R	10.4	Viable, dermal fibrosis	Patent	Narrowed	Intact	Vein sl. Purple
D1/L	10.4	Viable, dermal edema	Partial occlusion	> occlusion than vein	Intact	Narrowing
D2/R	10.4	Viable, dermal fibrosis	Sl. altered, but patent	Sl. altered, but patent	Small area of blanching	Patent, sl. darkening
D2/L	10.4	Viable, dermal fibrosis	Patent	Tiny, vessel collapsed	Small area of blanching	Patent, sl. darkening
C1/R	12.0	Viable, dermal fibrosis	Micro-thrombosis	Patent	Sl. blanching	Vein segmentally narrowed
C1/L	12.0	Viable, dermal fibrosis	Ghosted, without endothelium, but patent. Venular congestion	Narrowed and focally thrombosed	Sl. blanching	Vein narrowed segmentally
C2/R	12.0	Viable, dermal fibrosis	Organization with evidence of recanalization	Not described	Mild blanching	Vein narrowed segmentally
C2/L	11.6	Viable, dermal fibrosis	Thrombosis with organization	Not described	Mild blanching	Vein narrowed segmentally
B1/R	14.0	Viable, dermal fibrosis	Patent; not well seen in areas of fibrosis	Not well visualized	Mild blanching	Vessel seen
B1/L	13.7	Viable, dermal fibrosis	Ghosted, necrotic, contains blood	Patent	Mild blanching	Vessel seen
B2/R	14.0	Viable, dermal fibrosis	Patent	Lumina narrowed by intimal hyperplasia	Mild blanching	Vessel seen

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TABLE 4
ANIMAL STUDY PROTOCOL NP970208

No Cooling

Rabbit	Joules	Histology- Tissue	Histology- Vein	Histology- Artery	Clinical- Tissue	Clinical- Vessels
B2/L	13.6	Viable, dermal fibrosis	Occlusion focally	Not described	Minimal changes	Vein narrowed seg- mentally
A7/R	16.0	Viable, dermal fibrosis	Focally occluded	Focally occluded	Minimal changes	Mild blushing around vein
A7/L	16.3	Viable, dermal fibrosis	Partial occlusion, congestion of venules	> occlusion than vein	Mild induration	Blushing around vein
A6/R	15.5	Viable, dermal fibrosis	Patent	Focal occlusion	Minimal changes	Veins seen
A6/L	15.5	Viable, dermal fibrosis	Focally absent	Focally absent	Mild blanching	Vein seg- mentally narrowed
A5/R	17.4	Viable, dermal fibrosis	Thrombosis with organization	Thrombosis with organization	Mild blanching	Vein narrowed
A5/L	17.5	Viable, scale crust present, dermal fibrosis	Occlusion (organ- ization)	Not described	Mild to moderate induration	Vein narrowed

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CLAIMS

What is claimed:

1. The method of treating a subcutaneous histological feature within a
5 given depth range in the human body with microwave energy comprising the steps
of selecting a microwave frequency in which the loss factor of the target feature is
greater than that of adjacent tissue; and directing microwave energy at the chosen
frequency into the skin with a power density and for a time sufficient to raise the
10 temperature of the target feature to a level resulting in a permanent pathological
change in the target feature due to interaction of the electric field of the
microwaves with the target tissue without resulting in a permanent pathological
change in the intermediate skin.

2. The method as set forth in claim 1 above, including the step of
15 spreading the microwave energy with a distributed energy throughout an area at the
depth of the target feature.

3. The method as set forth in claim 2 above, including the further step
of cooling the intermediate skin depth between the surface and the target feature
20 during at least a portion of the treatment.

4. The method as set forth in claim 1 above, wherein the target feature
comprises hair and the interaction of the electrical field of the microwaves with the
hair induces preferential heating of the hair to cause permanent destruction of the
25 follicles.

5. The method as set forth in claim 4 above, wherein the target feature
comprises hair roots in the range of about 5 mm below the skin surface, and
wherein the method further includes the step of controlling the intensity and
30 duration of the microwave energy to radiate the target feature with 10 to 15 Joules
of energy.

6. The method as set forth in claim 1 above, wherein the target feature
comprises externally visible blood vessels of about 0.1 mm diameter or greater and
35 within 2 mm or less of the surface, and wherein the microwave energy thromboses

the blood in the target vessels by raising the blood temperature to in excess of about 55°C.

7. The method as set forth in claim 6 above, wherein the microwave frequency is in the range of 10–20 GHz, the applied energy is in the range of 20 to 30 Joules, and the duration is shorter than the thermal relaxation time of the blood vessels in the target features.

8. The method of effecting a pathological change with microwave energy in a subsurface area below human skin level without damaging the skin itself comprising the steps of:

delivering, toward the skin surface adjacent the subsurface area, a pulse of microwave radiation in the frequency range of 10–20 GHz at an energy level and for a time sufficient to deliver 10–30 Joules of energy;

- 15 shaping the radiation pattern of the pulse to distribute substantial energy throughout an area of greater than about 20 mm²; and

cooling the skin's surface during at least a portion of the pulse delivery interval period.

- 20 9. The method as set forth in claim 8 above, wherein the pulse duration is less than 200 milliseconds, and wherein the subsurface area is raised to a temperature in the range of about 55°C to 70°C.

10. The method as set forth in claim 9 above, wherein the pulse of microwave radiation is delivered to the skin surface across a transmission distance in excess of about .05 cm, and further including the step of injecting coolant in the transmission distance and against the skin surface.

11. The method as set forth in claim 10 above, wherein the coolant is delivered by expending a compressed gas in the volume including the transmission distance.

12. The method as set forth in claim 9 above, wherein the surface is cooled by conducting heat away from the surface by contact.

13. The method of effecting pathological change in a subcutaneous histological target region by external application comprising the steps of:

selecting a microwave frequency in the range of 10-20 GHz in which the loss factor for the histological target is greater than that for skin;

5 generating a signal at the selected microwave frequency;

propagating the generated microwave signals onto an area of the skin adjacent the subcutaneous region and greater than about 20 mm² in area while spreading the signal energy across the chosen area of the skin; and

10 maintaining the propagated signals for a time and until the impinging signal energy has reached a magnitude of about 10 to 30 Joules.

14. The method as set forth in claim 13 above, further including the step of cooling the chosen area of the skin during at least a portion of the duration of the interval of application of the microwave signals.

15

15. The method as set forth in claim 13, wherein the step of propagating microwave signals onto an area of the skin is effected by launching the microwave energy at a selected spacing from the skin surface, and wherein the skin cooling is effected by injecting a cooling gas into the space between the point of launching and the skin surface.

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16. A method as set forth in claim 13 above, wherein the microwave frequency is about 14 GHz, wherein the chosen area of the skin is in the range of 20 to 125 mm² and wherein the gap between the point of launching and the skin surface is in the range of 0.25 to 0.75 mm.

25

17. A method as set forth in claim 13 above, wherein the target region comprises a plurality of hair follicles in the chosen area, and wherein the energy delivered is in the range of 10 to 20 Joules.

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18. A method as set forth in claim 13 above, wherein the target region comprises blood vessels at depths of about 5 mm or less and wherein the energy delivered is in the range of 20-30 Joules.

19. A method as set forth in claim 13 above, further including the steps of preliminarily determining the reflected energy loss for the selected frequency, and tuning the frequency to reduce the reflection to less than about 5%.

5 20. The method of painless and permanent depilation of parts of the surface of a human body comprising the steps of:

 irradiating the surface with electromagnetic wave energy at a frequency that interacts with hair structure preferentially relative to skin tissue;

 locally heating a number of hair follicles in a defined surface area
10 with the wave energy while concurrently cooling the skin surface during at least a part of the heating; and

 maintaining the heating for less than one second at a sufficient power level to irreversibly damage the hair follicles in the defined surface area.

15 21. The method as set forth in claim 20 above, further including the step of repeating the sequence at different surface areas until an entire chosen area is depilated.

 22. The method as set forth in claim 20 above, wherein the defined
20 surface area is greater than 20 mm² and the levels of the irradiating wave energy are spread throughout the chosen area so that depilation of a number of hair follicles occurs simultaneously.

 23. The method as set forth in claim 22 above, wherein the energy
25 delivered, by virtue of the wattage and duration of the irradiation, is in the range of 10-20 Joules.

 24. The method as set forth in claim 23 above, wherein the irradiation is
30 maintained for in the range of 10 to 1,000 milliseconds.

 25. The method as set forth in claim 20 above, and further including the step of cooling the skin surface during at least a part of the irradiation interval.

 26. The method as set forth in claim 25 above, wherein the skin is
35 irradiated across a spacing and the cooling is effected by injecting an expanding cooling gas into the spacing and against the skin surface.

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27. The method as set forth in claim 20 above, and further including the steps of irradiating the skin surface through a member defining a target area adhered to the skin and removing the member with destroyed follicles adhering to it after irradiation.

28. The method of treating embedded blood vessels so as to cause their disappearance, comprising the steps of:
delivering areally confined wave energy in a microwave band to a target skin surface area proximate the target vessels;
distributing the confined wave energy across the selected area; and
propagating the distributed wave energy into the selected area to deliver at least approximately 10 Joules of energy in less than about one second; and
cooling the target skin surface area during at least a portion of the target skin surface area.

29. A method as set forth in claim 28 above further including the steps of locating reticular veins in communication with the embedded blood vessels, directing the wave energy to the located reticular veins, and delivering adequate energy to the reticular veins to heat the blood therein to in excess of 70°C so as to necrose vessel tissue.

30. The method as set forth in claim 28 above, wherein the wave energy is in the frequency range of 2.45 to 18 GHz.

31. The invention as set forth in claim 30 above, wherein the wave energy is in the range of 14 GHz, wherein the amount of energy delivered is in the range of 20–30 Joules, and wherein the duration of the delivery is of about 100 milliseconds.

32. The method of claim 28 above, further including the step of currently withdrawing, during propagation of wave energy to the skin surface, thermal energy from the skin surface to maintain the skin surface below a discomfort level.

33. The method of claim 32 above, wherein the step of withdrawing thermal energy comprises injecting an expanding cooling gas against the skin.

34. The method as set forth in claim 28 above, further including the steps of pre-examining the characteristics of the target area before application of wave energy, and positioning the wave energy being delivered in accordance with the pre-examined position to target chosen depths and sizes of vessels.

35. The method as set forth in claim 28, further including the steps of pretesting the dielectric and loss characteristics of the skin in a desired area, and adjusting the characteristics of the wave energy in accordance with pretest results to minimize reflected power.

36. The invention as set forth in claim 28 above, including the steps of calculating the approximate relaxation time of a target area in accordance with size, tissue character and the relaxation time, τ , expressed as $d^2/16\alpha$, wherein d is the diameter of the target and α is the thermal diffusivity.

37. The method of claim 28, further comprising the step of applying a substance from the class of substances comprising topical anesthetics and conductive substances that do not attenuate or reflect microwave energy to the skin surface.

38. The method of eliminating visible skin disorders caused by visible blood flows near the skin surface, comprising the steps of:

locating target vessels further below the skin surface than the visible vessels;

directing a microwave beam toward the target vessels at a frequency that is preferentially absorbed by blood in comparison to surrounding skin surface and tissue; and

maintaining the microwave beam and energy level and for a time sufficient to heat blood in the reticular vessel to in excess of 70°C and cause necrosis of the vessel, thereby terminating blood flow to the vessel/veins near the surface.

39. The method of permanently eliminating a subsurface telangiectasia condition comprising the steps of:

generating electromagnetic wave energy at a frequency, in the range of 2-20 GHz, which is preferentially absorbed by blood in relation to surrounding tissue;

propagating distributed microwave energy toward a target area of the skin facing the area of the telangiectasia condition;

maintaining the microwave energy application for a time sufficient to heat the blood in the veins having the telangiectasia to a temperature of about 70°C, such as to thermocoagulate blood in the target such that blood flow is permanently stopped;

cooling the surface layer of skin facing the area of the telangiectasia condition at least during a part of the microwave energy application to cool the skin to a depth shallower than the telangiectasia to prevent discomfort and surface damage without inhibiting thermocoagulation.

40. The method as set forth in claim 39 above, wherein the propagated microwave energy is the frequency range of 10-20 GHz and further including the step of establishing a field distribution within the selected target area which is greater than 25 mm², with an electric field strength distribution spread across the area, and wherein the exposure is in the range of 20-30 Joules.

41. The method as set forth in claim 40 above, wherein the duration of the propagated microwave energy is held for shorter than the thermal relaxation time of the veins exhibiting the telangiectasia condition.

42. A system for applying microwave energy to a body to heat specific internal volumes under the skin of a patient to eliminate visible skin disorders, comprising the combination of:

tunable power generator means, the power generator means operating in the microwave band and including power amplifier means and means for generating energy pulses of selected duration;

an applicator head for generating a beam of microwave energy directed at the skin surface at positions selected by an operator, the applicator head including interior dielectric beam shaping means for spreading wave energy in the beam throughout a power distribution area at the skin surface; and

microwave transmission means coupling the power generator means to the applicator head.

43. A system as set forth in claim 42 above, wherein the system further includes means adjustable by an operator for tuning the power generator means within a frequency range of 2.45 to 18 GHz, and means for measuring transmitted power and reflected power.

44. A system as set forth in claim 43 above, wherein the system further includes means responsive to the power measurements for tuning the power generator to increase efficiency by reducing reflection loss.

45. The system as set forth in claim 42 above, wherein the wave transmission means comprises a flexible line allowing manipulation of the applicator head and wherein the applicator head comprises a waveguide, and the dielectric beam shaping means includes at least one longitudinal element within the waveguide and having a high dielectric constant.

46. A system as set forth in claim 45 above, further including means coupled to the applicator head for cooling parts of the skin surface adjacent to the applicator head.

47. A system as set forth in claim 42 above, further including means at the applicator head for measuring the temperature of the skin surface during application.

48. A system as set forth in claim 42 above, including means for limiting pressure exerted on the skin surface during the application.

49. A system for treating subcutaneous histological target features with microwave energy to effect pathological change in such features comprising:

a source of microwave energy tunable in the range from 10-20 GHz;

a controllable element coupled to the source of microwave energy to deliver microwave energy pulses in response to control signals;

a microwave energy delivery device coupled to the controllable switch and including a microwave delivery port of less than about 150 mm² in area;

a cooling device including a controllable flow gating element, a source of pressurized coolant, and a coolant delivery channel adjacent the microwave delivery port; and

a control system for providing control signals to operate the controllable element and the flow gating element in timed relation for selected durations.

- 10 50. A system as set forth in claim 49 above, wherein the microwave energy delivery device includes a spacer element attached to the microwave delivery port and configured to provide a standoff volume providing a gap between the port and a skin surface in the range of 0.25 to 0.75 mm in contact with the skin surface wherein the coolant delivery channel extends through the spacer element
- 15 and wherein the controllable flow gating element comprises a solenoid-operated valve.

51. A system as set forth in claim 50 above, wherein the microwave energy delivery device comprises a hand-held applicator including a waveguide transition section including a wave concentrating dielectric and terminating in a
- 20 microwave delivery port, and wherein the system further includes a manipulable waveguide device coupling the source of microwave energy to the hand-held applicator.

- 25 52. A device for delivering microwave energy at a skin surface for propagation into a body for therapeutic treatment comprising:
- an open ended wave transmission line; and
- a dielectric insert disposed in the open end of the wave transmission line, the dielectric insert being selected to match the dielectric constant of the
- 30 portion of the body into which the microwave energy is to be propagated, and configured to spread the electric field.

53. A device as set forth in claim 52 above, wherein the applicator head further includes means for cooling the skin surface.

ABSTRACT OF THE DISCLOSURE

A system and method for treating subcutaneous histological features without affecting adjacent tissues adversely employs microwave energy of selected power, frequency and duration to penetrate subcutaneous tissue and heat target areas with optimum doses to permanently affect the undesirable features. The frequency chosen preferentially interacts with the target as opposed to adjacent tissue, and the microwave energy is delivered as a short pulse causing minimal discomfort and side effects. By distributing microwave energy at the skin over an area and adjusting power and frequency, different conditions, such as hirsutism and telangiectasia, can be effectively treated.

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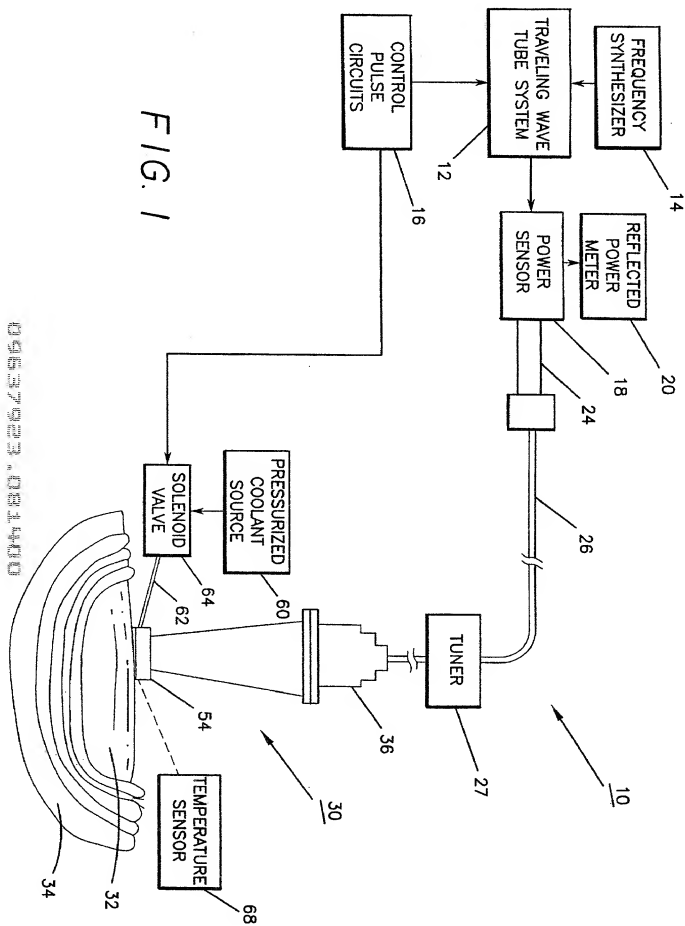


FIG. 1

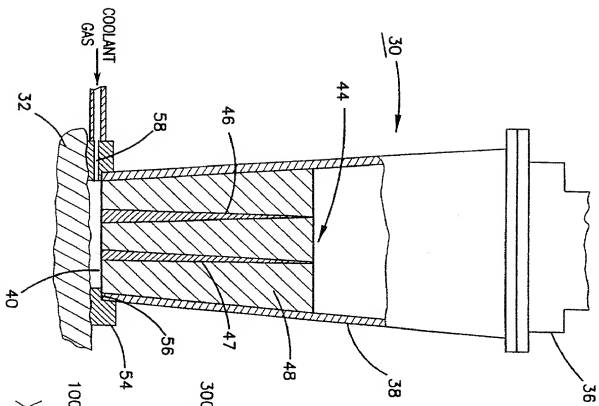


FIG. 2

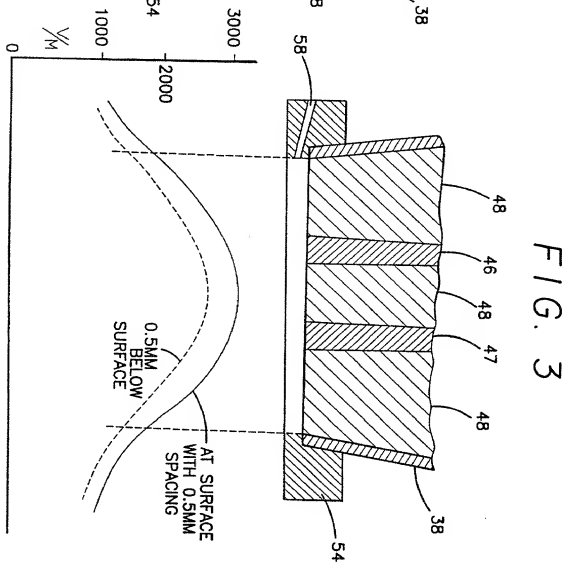


FIG. 3

HORIZONTAL ELECTRIC FIELD DISTRIBUTION
(COMPUTER MODELED)

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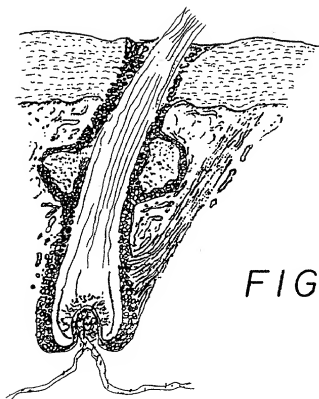


FIG. 5

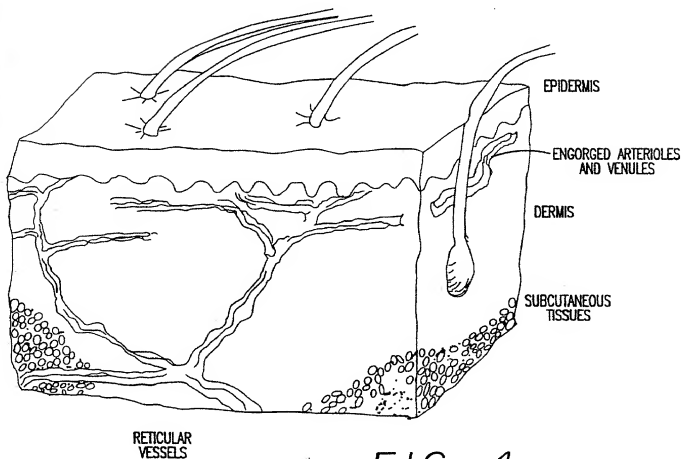
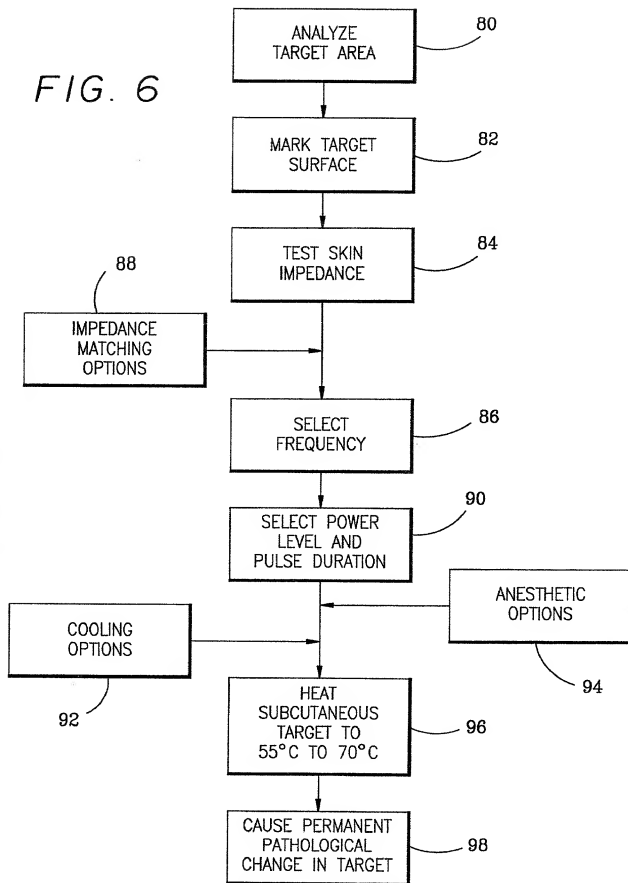


FIG. 4

FIG. 6



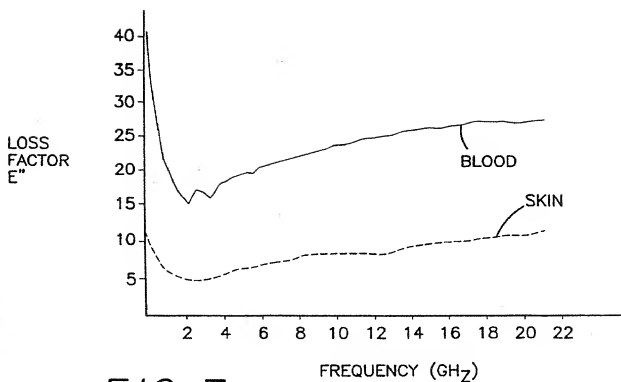


FIG. 7

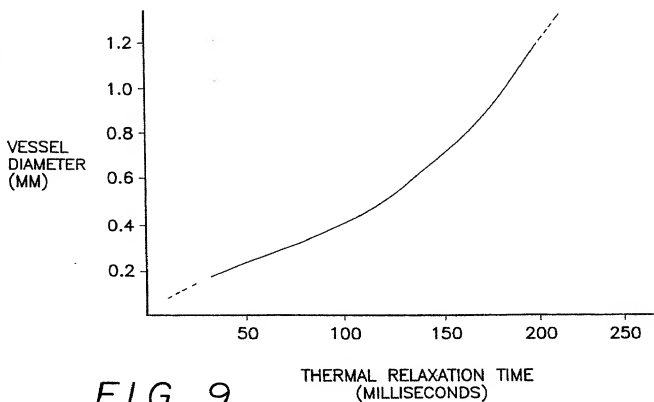


FIG. 9

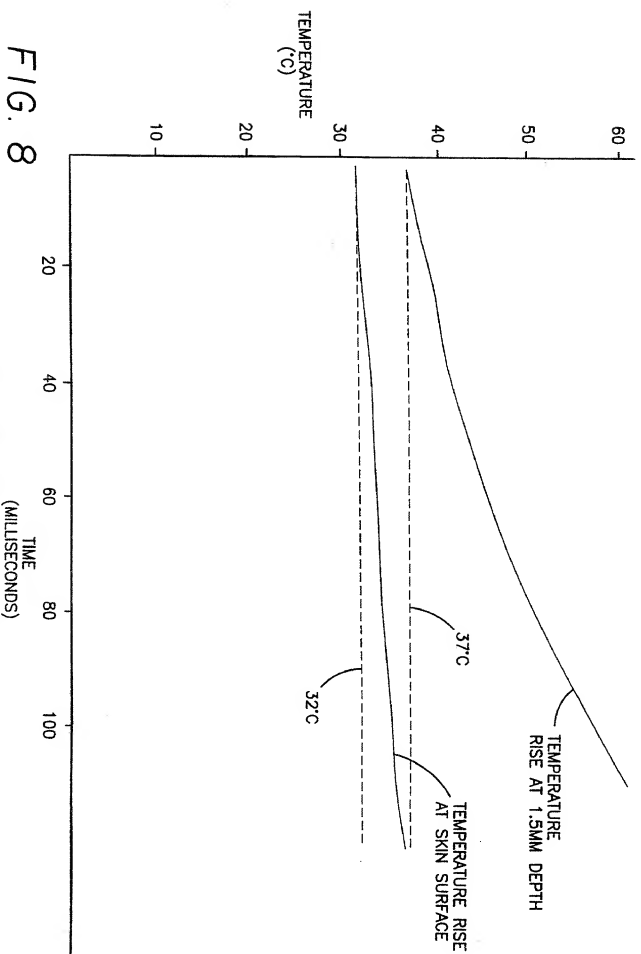


FIG. 8

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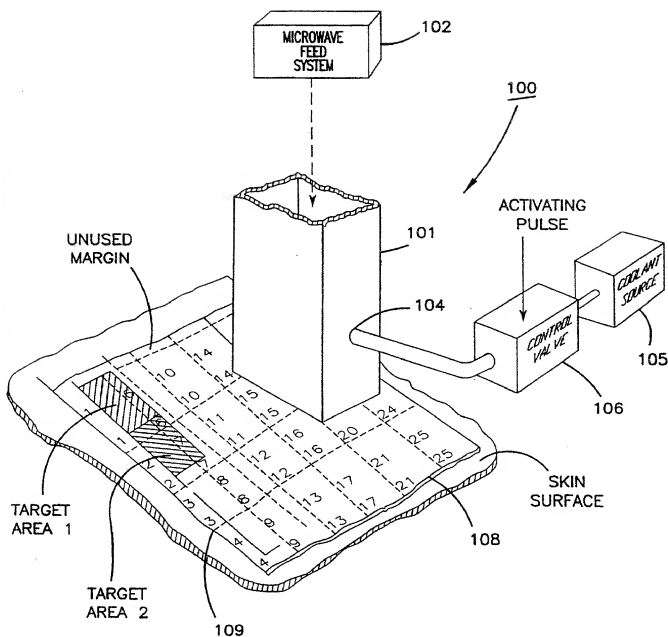
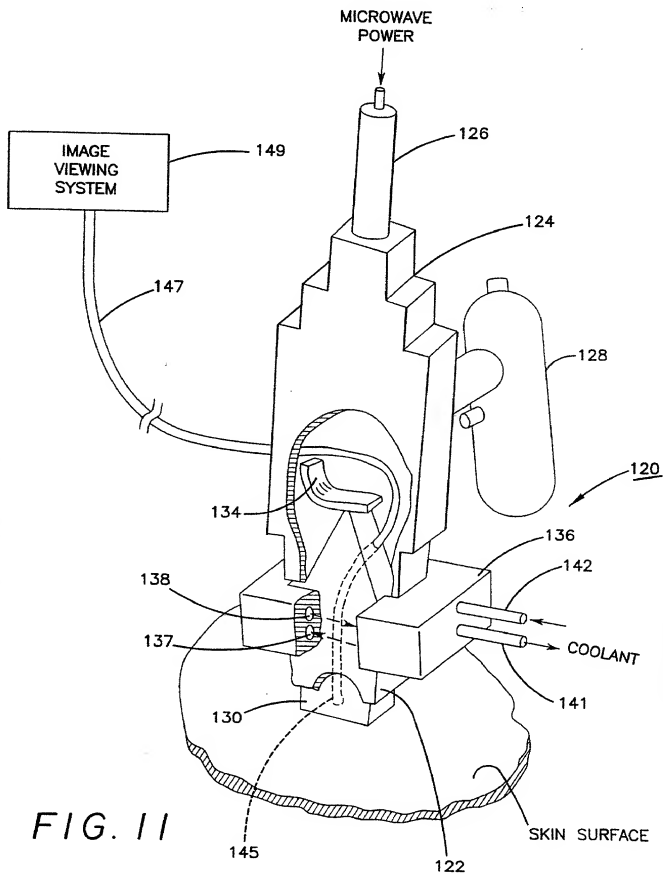


FIG. 10



COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

This declaration is of the following type:

- ☐ original
- ☐ design
- ☐ supplemental
- ☐ national stage of PCT
- ☒ divisional
- ☐ continuation
- ☐ continuation-in-part (CIP)

My residence, post office address and citizenship are as stated next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed for and for which a patent is sought on the invention entitled:

METHOD AND APPARATUS FOR TREATING SUBCUTANEOUS HISTOLOGICAL FEATURES

the specification of which

☒ is attached hereto

☒ was filed on July 31, 1997, as

Application No. 08/904,175

and was amended on _____

(if applicable)

☐ was described and claimed in PCT International application

No. _____ filed on _____

and as amended under PCT Article 19 on _____

(if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any Amendment referred to above.

I acknowledge duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

☐ In compliance with this duty there is attached an information disclosure statement. 37 CFR 1.97.

I hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119, of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

☒ no such applications have been filed

☐ such applications have been filed as follows.

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Prior Foreign Application(s)

<u> </u>	<u> </u>	<u> </u>	<u> [] </u>	<u> [] </u>
(Number)	(Country)	(D/M/Y filed)	Yes	No
<u> </u>	<u> </u>	<u> </u>	<u> [] </u>	<u> [] </u>
(Number)	(Country)	(D/M/Y filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code,
§ 119(e) of any United States provisional application(s) listed below:

<u> </u>	<u> </u>	<u> </u>
(Appl. Serial No.)	(Filing Date)	(patented, pending, abandoned)
<u> </u>	<u> </u>	<u> </u>
(Appl. Serial No.)	(Filing Date)	(patented, pending, abandoned)

I hereby claim the benefit under Title 35, United States Code, Sec. 120 of any United States application(s) listed below, and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Sec. 112, I acknowledge the duty to disclose all information known to be material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

<u>08/904,175</u>	<u>July 31, 1997</u>	<u>Pending</u>
(Appl. Serial No.)	(Filing Date)	(patented, pending, abandoned)
<u> </u>	<u> </u>	<u> </u>
(Appl. Serial No.)	(Filing Date)	(patented, pending, abandoned)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor ROBERT BRUCE SPERTELL

Inventor's signature *Robert Bruce Spertell* Date 1/9/00

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Residence _____

Citizenship _____

Post Office Address _____

Full name of third inventor _____

Inventor's signature _____ Date _____

Residence _____

Citizenship _____

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